



# *Preparing your CTU Application*



# *Preparing your CTU Application*

## *Before You Begin Writing*

- Perform a self-assessment
  - Expertise available
  - Documented experience
  - Patient base
  - Scientific strengths as they relate to the high priority research areas
  - Potential Network affiliations
  - Need for or potential benefits of a Mentoring Plan



# *Preparing your CTU Application*

## *Before you Begin Writing*

### ✚ Establish lines of communication

#### ▣ Develop appropriate linkages

- Network Leadership Group
- Emerging Clinical Trials Unit
- Potential Clinical Research Sites



## *Preparing your CTU Application*

### *Before you Begin Writing*

- Determine whether your resources, expertise and patient base are best suited for a Clinical Trials Unit application or as a Clinical Research Site within a Unit
- Draft an organizational plan and work with investigators involved to formulate the final decision



## *Preparing your CTU Application*

### *Before you Begin Writing*

- Become familiar with the Form 398 application and instructions
  - Face Page
  - Budget Pages
  - Resources and Environment page
- Review the special instructions presented in the RFA and on the DAIDS website



# *Preparing your CTU Application*

## *Research Plan*

### • Prepare as separate sections

- Clinical Trials Unit (10 pages)
  - 10 pages for first high priority research area or network affiliation
- Clinical Research Site (10 pages for each site proposed)



# *Preparing your CTU Application*

## *Research Plan*

### ● Clinical Trials Unit

■ A total of 10 pages available for:

- Overall Clinical Trials Unit and Administrative Component
- Contributions to Network Clinical Research Plans
- Plans for Community Interactions



## *Preparing your CTU Application*

### *Research Plan*



#### Overall Clinical Trials Unit and Administrative Component

1. Description of applicant organization
2. Diagram the organization of the CTU
3. Proposed Management & Communications Plan
  - Lines of authority
  - Decision-making process
4. Standard Operating Procedures for day-to-day operations





# *Preparing your CTU Application*

## *Research Plan*

- Overall Clinical Trials Unit and Administrative Component
  - 5. Oversight of Clinical Research Sites
    - Plans for close mentoring and supervision
    - Oversight of day-to-day operations
    - Ensuring that minimal enrollment goals are met
      - 20 patients average census per month
      - 100 patient average census for Phase III/IV trials



# *Preparing your CTU Application*

## *Research Plan*

### ● Overall Clinical Trials Unit and Administrative Component

#### 5. Oversight of Clinical Research Sites

- Ensuring Compliance

- USA Federal Regulations
- NIH/DAIDS policies and procedures
- DAIDS Pharmacy Guidelines
- Assure DAIDS approval of sites establishment plans and clinical protocols prior to initiating clinical studies



# *Preparing your CTU Application*

## *Research Plan*

- Overall Clinical Trials Unit and Administrative Component
  - 5. Oversight of Clinical Research Sites
    - Clinical Laboratory needs as determined by the Networks leadership
    - Collection, storage and reporting of clinical trials data



# *Preparing your CTU Application*

## *Research Plan*

- Overall Clinical Trials Unit and Administrative Component
  - 6. Expertise, experience and prior scientific contributions of key personnel
    - Principal Investigator and other key staff
      - Ability to lead, contribute to and prioritize research activities
      - Capacity to conduct clinical research in the relevant priority research areas.



## *Preparing your CTU Application*

### *Research Plan*

- Overall Clinical Trials Unit and Administrative Component
  - 7. Rationale for selection of each Clinical Research Site and its expected contributions
  - 8. Transition plan for ongoing DAIDS-sponsored clinical research activities, if any



## *Preparing your CTU Application*

### *Research Plan*



#### Contribution to Network Clinical Research Plans

1. Identify specific HIV Clinical Trials Networks and scientific priority clinical research areas to which the CTU is proposing affiliation
2. If specific Networks not yet identified, specify priority clinical research areas to be addressed
3. Each priority research area should be linked to specific Clinical Research Site(s)



# *Preparing your CTU Application*

## *Research Plan*



### Community Interactions

1. Plans to achieve meaningful partnerships
  - Outreach activities
  - Community education activities
2. Plans to establish Community Advisory Board(s)
  - Boards may be described at Clinical Research Sites
  - CTU section should describe overall structure and support for these activities at the various Clinical Research Sites.



# *Preparing your CTU Application*

## *Research Plan*



### Clinical Research Sites

#### 1. Description of Site

- Identify staff and describe their qualifications
- Describe the site infrastructure
  - Clinical services
  - Pharmacy
  - Laboratory services
  - Facilities for specimen and document storage





# *Preparing your CTU Application*

## *Research Plan*

- Clinical Research Sites
  - 2. Prior accomplishments of Site in HIV/AIDS multi-center trials
  - 3. Planned contributions to Network and/or priority research area



# *Preparing your CTU Application*

## *Research Plan*



### Clinical Research Sites

4. Patient Recruitment Plans
  - Screening of potential participants
  - Enrollment procedures
  - Retention plans
5. Staffing plans for management of enrollment
6. Plans to initiate recruitment within 6 months
7. Data management systems
8. Evidence of Institutional/Organizational support






# *Preparing your CTU Application*

## *Research Plan*

### Clinical Research Sites

#### 8. Plans for Community involvement

-  Community Advisory Board(s)
-  Specific plans for participation in all aspects of the research process
-  Outline resources available to the Community Advisory Board



# *Preparing your CTU Application*

## *Research Plan*

- Mentoring Partnerships (optional)
  1. Cover page and budget pages
    - Use the cover page provided on the website
    - Include Form 398 page 4 for detailed first year budget
    - Include Form 398 page 5 for budget for entire project period (limited to years 1-3)



# *Preparing your CTU Application*

## *Research Plan*

- Mentoring Partnerships
  - 2. Description (3 pages allowed)
    - Needs assessment – process and conclusions
    - Goals, objectives and scope of the plan
    - Specifics of mentoring plan with milestones
    - Expected benefits to mentored CTU
    - Roles of mentoring CTU staff
    - Plans to evaluate progress
    - If more than 1 mentoring CTU involved, delineate roles



# *Preparing your CTU Application*

## *Research Plan*

### ● Mentoring Partnerships

#### 3. Letters of Commitment

##### ■ Principal Investigator of Mentoring CTU

- Outline of support to be provided
- Describe involvement in needs assessment and plan formulation
- Planned activities and staff commitments



# *Preparing your CTU Application*

## *Research Plan*

- Human Subjects Research Section
  1. Risks assessment
    - Risks to research subjects
    - Adequacy of protection against risks
    - Potential benefits of proposed research
    - Importance of knowledge gained
  2. Inclusion of Women and Minorities
  3. Inclusion of Children as research subjects
  4. Complete the Targeted Enrollment Tables



# Targeted Tables

Principal Investigator/Program Director (Last, First, Middle):

## Targeted/Planned Enrollment Table

**This report format should NOT be used for data collection from study participants.**

Study Title: \_\_\_\_\_

Total Planned Enrollment: \_\_\_\_\_

| TARGETED/PLANNED ENROLLMENT: Number of Subjects   |            |       |       |
|---|------------|-------|-------|
| Ethnic Category                                   | Sex/Gender |       |       |
|   | Females    | Males | Total |
| Hispanic or Latino                                |            |       |       |
| Not Hispanic or Latino                            |            |       |       |
| <b>Ethnic Category: Total of All Subjects *</b>   |            |       |       |
| <b>Racial Categories</b>                          |            |       |       |
| American Indian/Alaska Native                     |            |       |       |
| Asian   |            |       |       |
| Native Hawaiian or Other Pacific Islander         |            |       |       |
| Black or African American                         |            |       |       |
| White   |            |       |       |
| <b>Racial Categories: Total of All Subjects *</b> |            |       |       |

\* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."